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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/828,668

04/21/2004

Igor Waysbeyn

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EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

12/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/828,668	<b>Applicant(s)</b> WAYSBEYN ET AL.	
	<b>Examiner</b> CHERYL MILLER	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11, 13, 15-24 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 13, 15-24, and 26-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 14, 2008 has been entered.

### ***Response to Arguments***

Applicant's arguments filed August 14, 2008 have been fully considered but they are not persuasive.

The applicant has argued that Fogarty (US 6,110,198) does not disclose a graft with a substantially constant cross-section along the length of the graft. The examiner disagrees. Fogarty discloses variation of the taper of the graft and shows in figure 4 different degrees of taper, some having zero, such as to have a substantially constant cross-section (see 94 in fig.4). The applicant also argues the components of Fogarty (62, 64, 66) must be implanted separately, thus not capable of being adjusted and fastened to one another before insertion. The examiner disagrees. Since Fogarty's components (graft 64/94, docking heads 62, 66; see fig.4) are separate they are *capable* of fitting to one another before or after insertion. Fogarty even discloses fitting (fastening) to one another prior to insertion such that the separate components are inserted as one device (col.7, lines 1-4; col.11, lines 36-39). The applicant has also argued that Fogarty discloses a resiliently expandable frame instead of a firm body, however a firm body is not claimed. The applicant argues that Fogarty's docking heads are not of one common

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material with constant properties along the length, however this is not claimed and it is not clear that this is even supported by applicant's specification. The applicant has argued the Fogarty does not disclose the claimed barbs. The examiner disagrees. Applicant has claimed, "a plurality of outwardly pointing and inclined barbs" connected to a docking head, which Fogarty appears to disclose, see barbs in figs.3b, 3c.

The applicant has argued that Baker (US 6,729,356 B1) does not disclose a docking head which consists of a monolithic single component, but instead a stent (44) and graft (40) combination. A single monolithic docking head is however not required by the claim. The claim requires a docking head comprising a truncated cone. Baker has shown in fig.1 for example a component (40; considered the docking head) attached to a graft (34), the component 40 has a stent (44) included on the component 40, thus the component may be considered a docking head, as it comprises a truncated cone (graft or stent of 40 both have a conical shape). Applicant has argued that their docking head is one component having an anchoring and sealing function as Baker's device has a sealing component 40 and anchoring component 44. However, since the two are attached to one another, the combination may be considered a "docking head".

Applicant has not claimed "stentless" docking head. How many parts make up the docking head (40) of Baker is irrelevant, as such is not claimed. Baker discloses the claimed invention. The applicant has also argued that Baker does not disclose inclined barbs. The examiner disagrees. Baker clearly shows in figure 1 and 3, barbs that extend outward and inclined away from the graft.

The applicant has argued that Elliot (US 2003/0236567 A1) is not combinable with Baker since Baker teaches placement of barbs on a stent, not on a graft. This is not found persuasive

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however since although Baker (and Randall) teach placement of barbs on stents, Elliot's docking head comprises a stent (resilient wires 22), thus it would be obvious to combine the two as barbs on Elliot's stent 22 is capable of piercing the body lumen as well for further anchoring and stent struts 22 are part of the "docking heads".

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11, 13, 15-24, and 26-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant has amended claim 11 to contain the phrase, "non-extendable" referring to the docking heads. No support was found by the examiner for the phrase "non-extendable". In applicant's arguments they argue the prior art is non-expandable, which is a little different, however support for this term was also not found. In fact, the docking heads are disclosed to be elastic, which would seemingly be extendable and expandable. Claims 13, 15-24, and 26-28 depend upon claim 11 and inherit all problems with the claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 11, 13, 15-24, and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 requires at least one second docking head (encompassing one or more). This is inconsistent with claim 11, as claim 11 not requires the graft to have a substantially constant cross-section along the length of the graft (seeming to point to the embodiment in figs.8-13). In this embodiment of a substantially constant cross-section (non-bifurcated), only one (not at least one) second docking head exists. Claims 13, 15-24, and 26-28 depend upon claim 11 and inherit all problems associated with the claim.

Claim 13 is indefinite as the graft may not have a substantially constant cross-section along its length and be bifurcated in the same embodiment.

Claim 15 is indefinite as a "suitable positioning" is not a structural object, but a position in space. Docking heads may not be coupled to a position or a point in space. It is suggested to change the claim to recite, --coupled to said graft at said suitable positioning by--.

Claims 16, 17, 18, 19, 23, 24, 26, and 27 each recite, "said truncated cone". It is unclear whether applicant is referring to both truncated cones (of the first and second docking heads) or one of them. If referring to one of them, it is unclear as to which applicant is referring to.

Claim 20 line 3 recites, "than the vessel is sized to so as to assume", which is unclear language.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 15-24, 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Fogarty et al. (US 6,110,198, cited previously). Fogarty discloses a device for treating an aneurysm (102; fig.5C) comprising a tubular graft (64/94) having a proximal and distal portions (two ends seen in fig.5C) and a substantially constant cross-section along the length of the graft (see fig.4; some of grafts 94 have constant cross-sections) and at least two non extendable (seem to not extend their length) docking heads (62, 66; see fig.4) comprising thin walled truncated cones (the heads are disclosed to be tapered or have flared ends, thus have truncated cone shaped ends; fig.3, 4, 6b; col.9, lines 58-61; col.18 line 57-col.20 line 25) a first docking head (62) at a proximal portion of the graft and a second docking head (66) at a distal portion of the graft, wherein the docking heads are movable with respect to and *adapted to* be adjusted and fastened to the graft before implantation (col.11, lines 36-40; Fogarty's docking heads 62, 66, may be attached to graft 64 by friction fit prior to implantation, and before attachment as they are separate components, they are movable with respect to one another), and a plurality of outwardly pointing and inclined barbs (83 or 85; figs.3b, 3c) connected to the docking heads (62, 66), the device capable of being coupled to a vessel on both sides of an aneurysm (102; fig.5c) by docking heads that act to guide, anchor and seal in a suture-less manner (stent of 62, 66 acts to anchor, the graft of 62, 66 acts to seal, and the proximal ends of 62, 66 act to guide into position as would the disclosed radiopaque markers that may be positioned on 62, 66).

Fogarty discloses the heads (62, 66) to be coupled to the graft (64) by fit. The docking heads are capable of and shown in the figures to be placed on either the inside or outside of graft

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and since the stents of the heads (62, 66) are expandable, they are capable of having many diameters smaller and larger than the graft and vessel wall. Fogarty's barbs (83) are flexible and inclined to the graft (see fig.3b). The barbs are shown to have a length *capable of* penetrating the vessel wall. Fogarty discloses barbs (85) that are concave and convex (the outer surface of 85 are convex and inner surface of 85 are concave). Fogarty discloses a hollow truncated cone (stent or graft of 62 or 66) has a plurality of open slits (apertures between stent struts considered slits OR slits 162 in graft; fig.9a) which allow expansion. Fogarty discloses the graft (64) and docking heads (62, 66) to be separate modules that are capable of being selected prior to insertion (fig.4). Fogarty shows docking head to be an outward eversion over the graft (is positioned on the outside of the graft; claim does not require the docking head to be an extension or monolithic with the graft).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 13, 15-24, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. (US 6,729,356 B1, cited previously). Baker discloses a vascular device (fig.1 for example) comprising a tubular graft (34) with proximal (top) and distal (bottom) ends and a substantially constant cross-section along the length (see figures), a first docking head (40+44) provided at the proximal end and a second docking head (disclosed to having multiple; col.4, lines 34-38) provided at the distal end. Baker's docking heads are "non-extendable", they



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are not shown to extend in length. Baker discloses the graft (134) to be tubular and bifurcated (col.2, lines 9-14, 18-24). Baker discloses the docking heads (40+44) to be truncated cones in shape (see fig.1; col.5, lines 26-28). Baker's docking heads are moveable and adapted to be adjusted and fastened to the graft prior to insertion (Baker's docking heads 40 are separate components sewn to the graft prior to implantation, thus are moveable and adjustable prior to attachment, which occurs prior to implantation thus meets the claim). Baker discloses the device to be capable of coupling to both sides of an aneurysm (col.4, lines 34-41; see fig.18 for example, showing a different embodiment at such a location), the docking heads capable of acting to guide (position at the ends of the graft, will provides the guiding since located at the most proximal and distal ends), anchor (stent 44 provides anchorage), and seal (graft of 40 provides seal). Baker discloses the vascular device substantially as claimed, however does not disclose a plurality of inclined barbs on the docking heads. Baker does disclose the use of barbs (43) on other portions of the device, such as on stent (38) in order to anchor the device to the vessel wall. It would have been obvious to one having ordinary skill in the art at the time the invention was made to additionally or instead place barbs on the stent 44 of the docking heads, since such a modification would involve a mere relocation or duplication of parts. Barbs are already used on one stent (38) of Baker that contacts the vessel wall, it would be obvious to place barbs on the docking head stent (44) since the docking head also contacts the vessel and would provide predictable results of anchorage at another location on the device. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) and also *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950).

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Claims 11, 15-20, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliot (US 2003/0236567 A1, cited previously) in view of Baker et al. (US 2002/0091439 A1, cited previously) OR Randall et al. (US 2003/0158595 A1, cited previously). Elliot discloses a vascular device (figs.3a-3c) comprising a graft (12) with proximal (top) and distal (bottom) ends and a substantially constant cross-section (see figs), a first docking head (16+22; includes stent 22) provided at the proximal end and a second docking head (multiple docking heads, P0026) provided at the distal end, the docking heads being truncated conical in shape (see fig.3b, 3c). Elliot discloses the graft (12) to be tubular (see figs). Elliot discloses attachment of the docking heads by sutures or bonding (P0030), and are shown and disclosed to be separate modules attached sometime before implantation, therefore, are capable of relative movement and positioning prior to attachment and prior to insertion, since attachment does occur prior to insertion. Elliot discloses the cone (16) to be an extension of the graft everted over itself (fig.3b). Elliot discloses the docking heads to be capable of coupling to the vessel wall and capable of guiding (guides due to the positioning on the ends), anchoring (stent frame 22 provides anchorage) and sealing (graft skirt 16 provides sealing). Elliot discloses the vascular device substantially as claimed, however does not disclose the use of inclined barbs. Baker and Randall each teach in the same field of vascular devices, the use of inclined barbs (195, concave, convex, etc; figs.21-24 of Baker; or 14, figs.1-3 of Randall) on stents (175, 176 of Baker or 10 of Randall) in order to penetrate and attach a graft (55) to the vessel wall and easy of insertion through a catheter (P0095; P0098 or Baker; P0017 of Randall). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Baker or Randall's teaching of using inclined barbs (195) on stents (175, 176), with the stents of docking

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heads (stent 22 of docking head) of Elliot, in order to provide better anchorage to the vessel wall with reduced trauma during insertion.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/  
Examiner, Art Unit 3738

/Corrine M McDermott/  
Supervisory Patent Examiner, Art Unit 3738

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